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A comparison of the views of patients and medical staff in relation to the process of informed consent

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ABSTRACT

INTRODUCTION The quality and quantity of information required in the consent process is well documented, but there is little extant literature regarding timing of either information about the proposed procedure or the act of consent itself. With the recent introduction of a new NHS-wide consent form, we wished to determine the preferences of both patients and staff to ascertain whether any concordance of views existed.

PATIENTS AND METHODS A 10-point questionnaire, developed in conjunction with the department of clinical psychology was completed by 242 patients selected for surgery over a 4-month period. Identical questionnaires were completed by local staff (n = 50) and national consultant plastic surgeons (n = 56).

RESULTS The cumulative majority (61.8%) preferred information at the specialist out-patient appointment (OPA). There was a significant difference ($P < 0.001$) between patients and staff as to information provision by the specialist as compared to non-specialists; staff indicating it much more strongly. As to the timing of consent form signature, 40.2% preferred signature on admission with no statistically significant difference between subgroups. An additional pre-operative clinic, for consent form signing, was selected by 27.3%. Staff expressed this view more often than patients ($P < 0.001$).

CONCLUSIONS Patients prefer information about a planned surgical procedure at their specialist OPA and final consent for surgery when admitted to the ward. Staff had quite definite views and felt an additional pre-operative out-patient appointment to be beneficial, more so than the patients themselves.

KEYWORDS

Consent form – Informed consent – Timing – Signature – Material risk

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Consent may be defined as the voluntary and continuing permission of the patient to receive treatment based on their understanding of the procedure and inherent risks in addition to its likely success and any alternatives. Consent for medical interventions has assumed greater importance with the advent of clinical governance and a more patient-orientated NHS.[1] Increasingly, patients become more aware of their basic rights, both ethically and legally, with consent now accepted as a right of the individual rather than of the clinician's duty of disclosure leading to challenge of the erstwhile automatic 'presumption of benifience'.[2] For so long the gold standard in the UK, the Bolam principle[3,4] – in essence any practitioner being protected in negligence proceedings if the level of information provided (including likely benefits and material risks) is similar to that of a 'reasonable body of medical peers' – has given way to other legal tests. Other countries operate under subtle, but fundamentally different, premises having rejected the English legal approach. North America, for example, well-known for its highly evolved litigation consciousness, bases its consent on virtually full disclosure of all known risks and this is considered 'informed consent' proper.[5] Legally, this is an 'objective' test whereby the decision is based on what a reasonable person in the patient's position would have decided upon if properly informed.[6] A different philosophy exists in Australia and New Zealand where the adequacy of information disclosed derives from a 'subjective' test of what risk the particular patient would determine acceptable to allow acceptance of the treatment.[7] The UK employs a 'hybrid' test of a reasonable patient in the position of the individual patient as the determining factor.[8]

The concept of 'material risk' is considered anything to which the patient would attach significance and is generally taken as any adverse event either occurring with a frequency of 1% or greater.[9] or infrequent, but severe, for example, blindness in blepharoplasty, which has a published incidence of 0.04%.[10] Interestingly, the 1% level, although widely employed, has not been tested in law[11] and

a recent New Zealand study reported that patients expressed the desire to be informed of serious risks with a frequency greater than 1-in-1000.[12] Most importantly, any explanation should be given in terms which the individual patient finds understandable.[13]

To emulate North American practice would have significant resource implications in an NHS chronically short of both relevant data-collection systems and man-power time. Moreover, UK practice has often erred on the side of caution, loosely based on 'therapeutic privilege' in the belief that unnecessary anxiety may be caused by imparting too much information about adverse effects, although this has been shown not to be the case of late.[14] Increasingly, the NHS is being driven towards a consultant-delivered service in which consultants are encouraged to participate in the obtaining of consent; a task hitherto routinely performed predominantly by junior staff.

In October 2002, the UK Department of Health (DH) introduced a new, NHS-wide consent form based on its document *12 key points on consent: the law in England* in which emphasis was placed on consent as an on-going process rather than the one-off event of merely obtaining the patient's signature.[15] There are three key elements to consent: first, that of the patient's capacity to have sufficient comprehension to make a rational judgement as to the benefits and risks to themselves of the proposed procedure. Second, consent must be obtained under neither duress nor coercion. Finally, has the patient been properly informed? It is the latter aspect on which this study focused having been stimulated by the paucity of published evidence regarding the timing[16] of both information provision and the obtaining of consent in an increasingly cognisant patient population. A further aim was to compare the views of patients as interested, but untrained, participants, with those of healthcare professionals in the question of both when information should be supplied and actual consent should be formally obtained.

Patients and Methods

A questionnaire (Appendix 1) was developed by the Department of Plastic Surgery in consultation with the Departments of Clinical Psychology and Medical Audit at the Royal Preston Hospital. It was deliberately designed for simplicity in order to focus on the key themes and maximise completion. Forms were distributed to consecutive patients under the care of the senior author. A total of 348 subjects were involved in the study: 242 patients and 101 medical staff. Seventy patients completed the questionnaire pre-operatively, 62 postoperatively and 110 patients who underwent local anaesthetic procedures. The second group provided a local, professional view and was subdivided into junior medical (20) and nursing (30) staff comprising the majority of the plastic surgery department. Finally, in an attempt to obtain a national consensus, all consultant plastic surgeons (with a valid e-mail address as registered by the British Association of Plastic Surgeons) were contacted electronically and replies received from 56.

Statistical analysis was performed using the χ^2 test with a value of $P < 0.05$ being considered significant as per standard convention.

Results

A total of 348 subjects were recruited to the study as detailed in Table 1 (information) and Table 2 (signature).

Timing of information

There was a clear consensus (61.8%) that overall delivery, in the form of both verbal explanation and information leaflets, was preferred at the pre-operative consultation with the specialist (Fig. 1). Much smaller proportions of 19.3% and 9.2% were indicated for the general practitioner (GP) and pre-operative clinic, respectively.

Sub-group analysis, presented as ratios in Table 3, demonstrated that there was a highly significant difference

Table 1 **Raw data of preferences of information provision for each subject group**

	Pre-operatively	Postoperatively	LA	Nurses	Juniors	Consultants	Total (%)
GP	14	11	33	6	1	2	67 (19.3)
Specialist	44	30	53	23	16	49	215 (61.8)
Pre-operatively OP	7	8	8	1	3	5	32 (9.2)
Admission	1	5	6	–	–	–	12 (3.4)
Nil	4	8	10	–	–	–	22 (6.3)
Total	70	62	110	30	20	56	

Table 2 Ratios of preference for information from the specialist compared to all other methods between subject groups

	Pre-operatively	Postoperatively	LA	Nurses	Juniors	Consultants
Specialist	44	30	53	23	16	49
Other	26	32	57	7	4	7
Ratio	1.7	0.9	0.9	3.3	4	7

($\chi^2 = 29.1$; $P < 0.001$) between patients and staff as to information provision by the specialist; the latter indicating it much more strongly whereas patients more frequently indicated satisfaction with this information at the point of initial contact with the GP.

Consent form signature

The situation was less clear-cut with respect to the timing of obtaining consent, taken as actual signing of the consent form by both patients and staff (Fig. 2). The overall majority (40.2%) view was for signature on admission to the hospital, with no statistically significant difference between subgroups ($\chi^2 = 0.15$; $P > 0.5$). A sizeable number (27.3%) felt that an additional pre-operative clinic would be the ideal location to sign the consent form and, once again, proportionately more staff than patients expressed this opinion (45.3% versus 19.4%; $P < 0.001$).

Discussion

Whilst it may be true that the standard of information imparted to patients in the past may have been somewhat variable leading to justified accusations of paternalism, clinicians are increasingly aware of the more informed patient who is capable of understanding, with appropriate explanation and discussion, the complex interactions between benefit and risk inherent in any intervention. Moreover, patients are increasingly keen to exert their moral right of self determination enshrined in the principle of moral autonomy.[1] Unfortunately, however, numerous studies have reported the often surprisingly poor level of information retention related to the consent process.[17–20] As a matter of great relevance to the patient, and medicolegally to the clinician, it has been shown that retained information may be frankly incorrect, yet strongly maintained, in an elegant study involving recorded consent acquisition of a group of patients well educated to their condition.[17] Such poor recall has been previously reported, particularly in the area of paediatric oncology where rates in excess of 30% have been shown.[21] Interestingly, the poorest recall is seen with respect to potential complications[15] and decreases with the occurrence of untoward events.[22]

Many factors have been demonstrated to influence information retention and recall. These include emotional state,[14,21] increased age, low IQ, cognitive impairment, an external health locus[25] the presence of a patient's 'signifi-

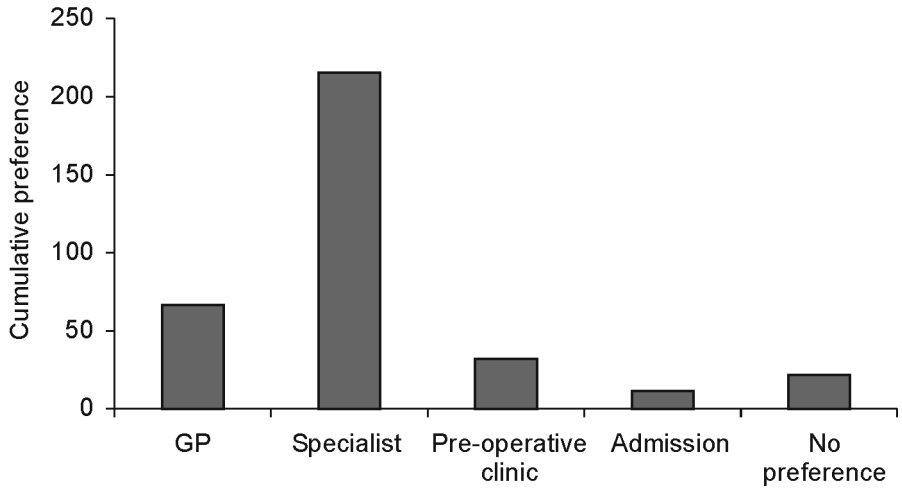

Figure 1 Cumulative preferences for provision of information.

Table 3 Raw data of preferences for timing of consent for each subject group

	Pre-operatively	Postoperatively	LA	Nurses	Juniors	Consultants	Total (%)
Specialist	19	17	25	9	–	7	77 (22.1)
Pre-operatively OP	25	14	8	13	11	24	95 (27.3)
Admission	18	23	58	8	8	25	140 (40.2)
En route	1	–	2	–	–	–	3 (0.9)
Nil	7	8	17	–	1	–	33 (9.6)

cant other',[24] multiple consultations,[19,22] printed information leaflets[25,26] and video.[27,28] The UK General Medical Council (GMC) now recommends the use of 'up-to-date written material, visual and other aids' in their guidance on consent.[1]

The current study shows that clinicians are in accordance with patients' wishes vis-à-vis provision of information as the majority view overall (61.8%) indicated that this should be supplied at the time of specialist consultation. Subgroup analysis, however, indicated that the clinicians (64.7%) felt this to be far more important than the patients (52.4%), particularly those postoperative and undergoing minor procedures (48.4% and 48.1%, respectively). Given the vested interests inherent to the staff side this is perhaps not so surprising, but may suggest that a subtle, unconscious, paternalism remains: nearly 40% of patients did not feel the need to receive specific, operative advice from the specialist and over half of these would have been happy to have obtained it from their GP.

The situation was less clear with respect to the act of consent form signing, but the majority (40.2%) preferred this on admission with no statistical difference between patients and staff. The next favoured (27.3%) option was in an additional pre-operative clinic shortly before the procedure. Although, this option attracted a minority view, there was a striking patient-to-staff difference (19.4% versus 45.3%; $P < 0.001$). It should be remembered, however, that the study involved predominantly minor-intermediate procedures involving short hospital stays, relatively limited intervention and consequently lower risk parameters, which may add some element of reporting bias. Interestingly, few suggested consent form signing at the specialist clinic and this may reflect either a lack of comfort with unfamiliar surroundings or a feeling of being allowed only a limited amount of time for such an important, decision-making process. It is important to understand that a signed form is by itself insufficient to validate, and therefore make lawful, consent; however, its completion provides evidence of at least some form of interlocution and warnings given and is regarded as good surgical practice.[29]

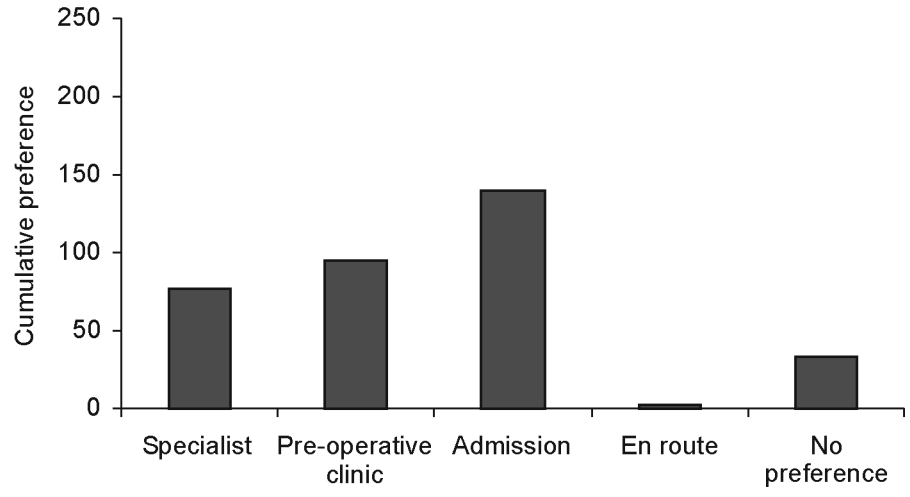

Figure 2 Cumulative preferences for timing of consent.

Although clinicians are being encouraged to obtain consent at the time of specialist visit, there are several reasons for this not to be ideal. A pilot study indicated that each form could add an additional 8–12 min to each out-patient slot if completed rigorously. Patients may have insufficient time to make an informed decision regarding the procedure and will have no opportunity to discuss it with absent family members. The clinician obtaining consent in out-patients may well not perform the surgical procedure, which may alter subsequent to a change in the patient's condition. Increasingly, consent is considered to be a process rather than one-off event and a 'cooling off' period, not dissimilar to the financial services industry, during which the patient may consider their position and possibly refuse to proceed, may become increasingly prevalent.

It was interesting to note how keen were staff to offer patients a further out-patient appointment, following initial consultation and shortly prior to admission, as compared to the patients themselves. As the category of proposed surgery was not stipulated within the questionnaire, further extrapolation is not possible. Pre-admission clinics are now well established and a useful addition to screen for occult co-morbidity in addition to allowing time for further discussion in more complex cases. At current rates, a single out-patient slot is costed at £58 in our unit so it will remain for health economists to decide whether an extra appointment is either necessity or luxury: this study found that patients did not indicate a strong preference for it.

One notable observation was that only one single clinician failed to express a preference (for consent signing) whereas 11.2% of patients were similarly unconcerned. Finally, none bar three, of 242 patients and no staff indicated willingness to sign the consent form en route to theatre.

It is worth emphasising that this was not intended to be a satisfaction survey, rather an information gathering exercise with the dual defined questions of addressing the timing of information provision and consent form signature. This was purposeful in an attempt to minimise the personal bias attendant upon the patient's experience with the entire clinical episode, be it good or bad. We do, however, recognise that solicited opinions cannot be entirely divorced from overall perception and that the different groups will have differing emphases. Additionally, practical matters might be influential, for example more medical than nursing staff preferred ward-based consent (40–45% cf. 27%).

Conclusions

Patients appear content with information being supplied by their specialist at the initial out-patient visit and, to a lesser extent, signing the consent form on admission. Staff had quite definite views and felt an additional pre-operative out-patient appointment to be beneficial, more so than the patients themselves. The practice of consent form signature en route to the operating theatre drew virtually no support and should rightly be considered an unacceptable part of contemporaneous practice.

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APPENDIX 1

Questionnaire used in the study

PLASTIC SURGERY DEPARTMENT

AUDIT ON INFORMATION LEAFLETS & CONSENT GIVING

The Plastic Surgery Department is interested in your view about the best time to give information to patients about an operation and the best time for patients to give their written consent to that operation.

The information you will give is confidential (we do not need your name) and will help us to plan better services.

Please tick your answers.

A Information about an operation

Information leaflets will soon be available for most operations. From your point of view, when would be the best time to receive an information leaflet about an operation?

Tick One Box

1. From your General Practitioner when he refers you to the Specialist ❑
2. From your Specialist in the Outpatient Clinic when he has decided to do the operation ❑
3. In a Pre-operative Clinic 1–2 weeks before the operation ❑
4. On the Ward, when you are admitted for the operation ❑
5. No preference ❑

PLEASE ADD ANY COMMENT OR EXPLANATION

B Consent To surgery

All patients having surgery have to give their signed consent before the operation.

From your point of view, what would be the best time to give written consent to surgery?

Tick One Box

1. In the Out-patient Clinic after the Specialist has explained the operation needed ❑
2. At a Pre-operative Clinic 1–2 weeks before the operation ❑
3. On the Ward, when you are admitted for surgery ❑
4. When you go down to Theatre, just before the surgery ❑
5. No preference ❑

PLEASE ADD ANY COMMENT OR EXPLANATION